	THOIVIC	Mal Case Safety	Report						1	CBEK	
			Y rep	orting of	Form A	Approved: Of	MB No. 09 \$e	910-0291, Expires: 6/30/ e PRA statement on rev	2015 erse.		
					uct pr	oblems and	Triage unit		DA USE ONLY		
	Adverse Event I	Reporting Program			1 of <u>₹</u>	2	sequence #	10/4	96	94	1
	A. PATIENT IN	IFORMATION	THE PARTY OF THE P		1 2	Dose or Amount	Frequ	anm.	Route		$\dashv$
		2. Age at Time of Event or	3. Sex	4. Weight		300 ml	once				$\neg$
	(b) (6)	Date of Birth: 74 years old	Female	145 <sub>jb</sub>		300 mi	once		COTON	овсору	$\ $
	In confidence	7-2-2-02-0	Male	or 65.9 kg	#2						$\exists$
		I EVENT, PRODUCT PRO	DBLEM OR EF		3. Da	ites of Use (if unknown	n, give duratio	n) from/to	5. Ever	nt Abated After Use	믝
	Check all that apply:				11	r best estimate) 5/27/2015				ed or Dose Reduced? Yes No Dose	snt
		t Product Problem (e.	20,0	100	11-	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			1	App	У
	2. Outcomes Attribu	uted to Adverse Event				agnosis or Reason for Recurrent C. Di		ion)		Yes No Doe App  App  AReappeared After	у
	Deeth: (D	) (6) Disat	ollity or Permanent	Damage		Infection	TITICITE		Rein	troduction?	
	Life-threstening	mm/dd/yyyy)	enital Anomaly/Birt	lh Defect	#2				#1 🔲	Yes ☐ No ☑ Doe App	У
		- initial or prolonged  Other			6. Lo	t#	7. Expiratio	n Date		Yes ☐ No ☑ Doe App	y y
	3. Date of Event (m	vention to Prevent Permanent I	mpairment/Damage e of this Report (n		#2		#2		9. NDC	# or Unique ID	
	07/2015		03/2015	нгисиуууу	ALCOHOLD STATE	SUSPECT MEDIC	AL DEVIC	Œ			200
		Problem or Product Use Erro screened for the fee		a	1 .,	and Name cal Microbiota	Transplan	nt			
		tudy 06-APR-2015, ar ransplant procedure			2. Cc	mmon Device Name			2h	. Procode	-
X	related dono completed wi	r. The 24-hour follo th the patient's sor			St	cool Transplant				CTU	
CKI	follow-up ph patient was	one call, patient's experiencing a mild	son reported	that the	3 M:	mufacturer Name Cin	and State	1.4		SEP 1 6 20	5
TYPE OR USE BLACK INK	patient's so hospitalizat	n answered negativel ion, fevers, chills,	y for abdomi	nal pain,		(b) (b)	, (b)	(4		OLI TW CO	94
SE	appetite, an	d constipation. The o completed with the	7-day follow	-up phone	4. Mc	odel#	Lot#			5. Operator of Device	
RU	JUN-2015. At	the 7-day follow-up n reported that the	phone call,	the	N/	A	N/A			✓ Health Profession	nal
E O	,	n seperate and and	pacient nao.	••	Ca N/	talog #	1	n Date (mm	v/dd/yyyy)	Lay User/Patient	
TY	& Reloyant Tortell	aboratory Data, Including Dat				1	N/A			Other:	
PLEASE	O. Resevant Testoria	boratory bate, including bar	ars.	la:	Se N/	rial# A	Unique Id	dentifier (UI	DI) #		
ZE					6. If I	mplanted, Give Date (	mm/dd/vyyy)	7. If Exp	lanted. C	Sive Date (mm/dd/yyy	<del>,  </del>
				8	05/	27/2015 his a Single-use Devi	-,,-,-				
				4		Yes V No					
					9. WY	es to Item No. 8, Enter	Name and Ade	ireas of Rep	processor		
	7. Other Relevant Hi allergies, race, pre History of L	story, including Preexisting and alcohol u	Medical Condition ise, liver/kidney pro	is (e.g., obiems, etc.)							
	Chronic obst	ructive pulmonary di resulting in resect		at om.	Charles and the Control of the Contr	THER (CONCON uct names and therap	A STATE OF THE PARTY OF THE PAR			AND THE RESERVE OF THE PARTY OF	
	Osteoarthrit	is of the hips acture requiring sur			Amic	darone (histori	ic medica	tion)		····	
	Bowel obstru Hypertension	ction	gery			opzzz (iizocoz	anouzeu	,			
	Left arm fra				C. F	REPORTER (See a	confidentia	lity sectio	on on b	ack)	
	C. PRODUCT A				1	h) /	61	1	h	1/1	1
		r Evaluation? (Do not send p				b) (	01.		U	1 (4	
		Returned to Manufacturer	on: (mm/	dd/yyyy)	1	/ /					119
		RODUGI((S)) lanufacturer (from product lab	el)								
	#1-Name:Strength:					6.5 saint sto					
	Manufacturer:	· · · · · · · · · · · · · · · · · · ·					Occupation		4	. Also Reported to:	
	#2 Name: Strength;				-	Yes No Phy ou do NOT want your ic	ysician dentity disclos	sed		☐ Manufacturer ☐ User Facility	
	Manufacturer:					he manufacturer, place				☐ Distributor/Import	er

11516262-01-00-02

IN PAGE)
Y reporting of iroduct problems

614964

Adverse Event Reporting Program

Page 3 of 3

B.5. Describe Event or Problem (continued)

experiencing moderate fatigue, mild loss of appetite, and moderate diarrhea. The patient's son answered negatively for abdominal pain, hospitalization, fever, and chills. Patient's son reported that the diarrhea had "gotten better". Patient and her son did not have any questions or concerns at this time. Due to the patient and clinic scheduling conflict, patient's 4-week follow-up appointment was not scheduled until 20-JUL-2015. No other adverse events were reported by the patient or patient's son during this time. Site became aware of patient's death when son called to cancel the scheduled the 4-week follow-up appointment on 20-JUL-2015 (approximately 2 months after the fecal transplant procedure). No medical information is available regarding the patient's death, for the medical records are at another hospital. Dr. (b) (6) and Dr. (b) (6) both called the patient's son to request additional information about the patient's death and obtain hospital records related to the patient's death, and neither of them were not able to reach the patient's son. Due to the patient's ongoing comorbidities noted during the screening visit and considering that 2 months had passed before the patient's death, investigators felt that the patient's death was not related to the FMT procedure. This report will be updated as more information becomes available.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

B.7. Other Relev	ant History, Including Pres	existing Medical Conditions (e.g., aller	gies, race, pregnancy, smoking and al	cohol use, hepatic/renal dysfunction, etc.) (continued)

Allergic to amoxicillin

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Lorazepam (historic medication) Sertraline (historic medication)

Folic acid (historic medication)

Aspirin Blmg (historic medication)

Calcium Carbonate-Vita D-Mineral (historic medication)

Dasatinib (historic medication)

Potassium Choloride (historic medication)

Furosemide (historic medication)

Fluticason-salmeterol (historic medication)

Levetiracetam (historic medication)

Metoprolol (historic medication)

DSS EP 16 201

Form Approved: OMB No. 0910-0291, Expires: 12/31/2011 See OMB statement on reverse. Individual Case Safety Report porting of Triage unit sequence # problems and TOTS Da. 11789390-01-00-01 Dose or Amount Frequency Route 1. Patient Identifier [2. Age at Time of Event or | 3. Sex once Date of Birth: (b) (6) √ Female Ib 52 Year #2 65 <sub>kg</sub> (b) (6) Mele In confidence 5. Event Abated After Use Stopped or Dose Reduced? Dates of Use (If unknown, give duration) from/to (or best estimate) B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR #1 Yes No Doesn't Apply Check all that apply: #1 11/24/2015 - 11/24/2015 1. Adverse Event Product Problem (e.g., defects/malfunctions) #2 Product Use Error Problem with Different Manufacturer of Same Medicine Doesn't Apply #2 Yes No 4. Diagnosis or Reason for Use (Indication) 2. Outcomes Attributed to Adverse Event (Check all that apply) 8. Event Reappeared After #1 recurrent C. diff infection Reintroduction? Disability or Permanent Damage Death: #1 Yes No Doesn't #2 (mm/dd/yyyy) Apply Congenital Anomaly/Birth Defect Life-threatening #2 Yes No Doesn'i 7. Expiration Date 6. Lot# Hospitalization - Initial or prolonged / Other Serious (Important Medical Events) #1 05/05/2016 #1 9. NDC # or Unique ID Required Intervention to Prevent Permanent Impairment/Damage (Devices) #2 #2 (b) (6)3. Date of Event (mm/dd/yyyy) 4. Date of this Report (mm/dd/yyyy) E. SUSPECT MEDICAL DEVICE 11/24/2015 11/25/2015 1 Brand Name 5. Describe Event, Problem or Product Use Error 2. Common Device Name CTU See additional page(s) for complete text. 3. Manufacturer Name, City and State PLEASE TYPE OR USE BLACK 3 0 2015 4. Model# Lot# 5. Operator of Device Health Professional Expiration Date (mm/dd/yyyy) Lay User/Patient Catalog # Other: 6. Relevant Tests/Laboratory Data, Including Dates Serial # Other # 7. If Explanted, Give Date (mm/dd/yyyy) 6. If Implanted, Give Date (mm/dd/yyyy) See additional page(s) for complete text. 8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No 9. If Yes to Item No. 8, Enter Name and Address of Reprocessor Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and elcohol use, liver/kidney problems, etc.) F. OTHER (CONCOMITANT) MEDICAL PRODUCTS Product names and therapy dates (exclude treatment of event) See additional page(s) for complete text. See additional page(s) for complete text. G. REPORTER (See confidentiality section on back) C. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) 1. Name, Strength, Manufacturer (from product label) #1 Mame: fecal microbiota preparation Strength:

FORM FDA 3500 (1/09)

Manufacturer:

Manufacturer:

#2 Name

Strength:

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Yes No

NOV 3 0 2015

2. Health Professional? 3. Occupation

5. If you do NOT want your identity disclosed

to the manufacturer, place an "X" in this box:

4. Also Reported to:

✓ Manufacturer

User Facility

Distributor/Importer



Patient received stool transplant product - Openbiome fecal microbiota preparation at 13:00 on 11/24 - and developed fever and WBC to 30 by 23:00. Patient previously stable. Possible connection to drug, not certain.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

11/24 23:15 temperature 101.3F, 11/24 23:59 WBC 30.9 ANC 26.8

B.7. Other Relevant History, Including Preexisting Medical Conditions smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued) (e.g., allergies, race, pregnancy,

Frequency

Chronically ill, ventilated long term subacute patient with recurrent C. diff from years of chronic antibiotic use for multidrug resistant organisms.

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Status Route &n bsp; Scheduled Description D/C \*Rx Communication - Vaccine administration R/0 Dispensed Commun ONCE (UNSCHEDULED) 10/01 0751 R/O bsp; D/C \*tobramycin Pharmacy Dosing Order Verified Commun &nbs p; PHARMACY
PROTOCOL 11/25 0659 -- R/O &n bsp; D/C artificial tears (LUBRIFRESH P.M.) Ophth
Oint Dispensed BOTH CONJUNC BID 06/22 2100 -- R/O &n bsp; D/C
atorvastatin (LIPITOR) Tab 80 mg Verified PEG TUBE EVERY BEDTIME 11/03 reminder OTH CONTROL OF STATE STA Route & mg Verified ORAL INHALAT Q2H PRN bisacodyl (DULCOLAX) Supp 10 mg Dispensed -- R/O &n bsp; D/C glycopyrrolate (ROBINUL) Tab 1
ispensed PO &nbs p; TID PRN 10/27 1808 -- R/O
e (PROAMATINE) Tab 5 mg Dispensed PEG TUBE Q6H PRN 1702 R/O &n bsp; D/C Dispensed midodrine (PROAMATINE) Tab 5 mg 09/18 1417 -- R/O 6n bsp; D/C sodium phosphates (FLEET) 1 Enema Dispensed nbsp; DAILY PRN 06/22 1702 -- R/O 6n bsp; D/C Continuous Description Status Route 6 nbsp; Frequency Start ; End R/O ; End F Verified IV and sp; CONTINUOUS 11/25 D/C NaCl 11/25 0715 R/O 0.45% IV Soln bsp; D/C

11809820-01-00-01



Form Approved: ONB No. 0910-0291, Expires: 6/30/2015

	INIEDAANI	LH		se events, proc	luct p	roblems and	Triage unit	FDA US	E ONLY	The sales	
	The FDA Safety Inform Adverse Event Report			Page			Triage unit sequence #	71	22	$\overline{}$	
	A. PATIENT INFORM				2.	Dose or Amount	Frequency	Rout	•		
	1. Patient Identifier 2. Age Pale (b) (6)	of Birth:	Female	4. Weight	#1	30 ml	XI		pper enlosu	מלח	
	In confidence  B. ADVERSE EVENT	T, PRODUCT PRO		ROR kg	3. D	lates of Use III unknown.	oive duration) fro	m/lo   5 E	vent Abated After i		
	Check all that apply:  1. Adverse Even!	Product Problem (e.g	., delecis/malluncu	ions)	111	ates of Use (If unknown, or best estimate)			pped or Dose Redu	iced?	
	Product Use Error		nt Manufacturer of	Same Medicine	1	lagnosis or Reason for I	Use (Indication)	#2	Yes No	-	
	(Check ell that apply)  Death:	_	ility or Permanent D	)amana	B1		SEC. L.	8. E	vent Reappeared A		
	Life-threatening	2007)	enital Anomaly/Birth	-	82	TO THE TOTAL P	1141000		Yes No 🗵	TDossn'i Apply	
	Hospitalization - initial o	or prolonged Other	Serious (Important	Medical Events)	6. Lo	"(h) (6)	7. Expiration Dat	#2 [	Yes No		
	Required Intervention to 3. Date of Event (mm/dd/yyy		npairmenVDamage of this Report (m		#2		12	9. N	DC # or Unique ID		
1	11-6-15		12-3-15		STATE OF THE PARTY NAMED IN	SUSPECT MEDICA	AL DEVICE				
	5. Describe Event, Problem				1. Br	rand Name					
	produ	we use	went a	علامر	2. Cc	ommon Device Name			2b. Procode		
ž	درب	the most	here.							w:	
Š	D <sub>1</sub>	meral (	(b) (6	3)	3. Ma	anufacturer Name, City a	ind State				
BL	product use went well with no serious obvience affects.  Pt. expensed (b) (6)  to other problems (see next form).										
USE	Ab.	Muer 1	form).		4. Mo	odel V	Lot#	***	5. Operator of		
g	( ^	DO VILYON	0		-	4-1			Health Profe		
TYPE OR USE BLACK INK						talog #	Expiration Dat	e (mm/dd/yy		itlent	
	6. Relevant Tests/Laboratory	Data, Including Date	18		So	rial #	Unique identifi	er (UDI) #	Other:		
PLEASE											
Ā		ĊŢŨ	*	Ī		mplanted, Give Date (mn			, Give Date (mm/dd		
- 1					8. ls t	ihis a Single-use Device Yes \tag{No}	that was Repro-	cessed and	Roused on a Patier	n1?	
L		DEC - 7				es to Item No. 8, Enter Na	me and Address	of Reprocess	104		
7	. Other Relevant History, Inc allergies, race, pregnancy, s	cluding Preexisting M moking and alcohol us	edical Conditions e, liver/kidney prob	(e.g., lems, etc.)							
- 1	Her. Ca O	vory, Bul	at. leg_		F. 0	THER (CONCOMIT	ANT) MEDIC	AL PROL	DUCTS		
	aupotol	vory, Bul	was, Evi	a, DM	Produ	uct names and therapy d	lates (exclude tre	atment of ev	rent)		
		/	·	,							
					G R	FPORTER (See con	oficientiality s	petion on	book		
10000	PRODUCT AVAILAR							1	01		
١.	roduci Available for Evaluat					10			<b>MAINTEN</b>		
L	SUSPECT PRODUC	med to Manufacturer o	m: (mp/dd	ומממו							
1.	Name, Strength, Manufactu	rer (from product label								Dec	
"1	Strength:	Transplant of	(b) (6)					1		100	
#2	Manufacturer: ppen	Bion.	(~) (~)		iλυ	Yes No	7		T. MISO REPUNES I	6 61115	
	Strength: Manufacturer,				5. If yo	ou de NOT want your Iden			User Fecility		
F	ORM FDA 3500 (2/13)	Submission of a	report does not co	onstitute an admis		he manufacturer, place an het medical personnel or		ed or contrib	Distributor/Im	porter	



11809820-01-00-02

## **MEDWATCH**

The FDA Safety Information and Adverse Event Reporting Program UATION PAGE

For VOLUNTARY reporting of adverse events and product problems

Page 3 of 3 B.5. Describe Event or Problem (continued) Pt. developed C. Difficle infection and was honresponsive to medication. A fecus transplant was
performed on 11/6/15 ma upper endoscopy, the
distrales reached within a few days. Pt was
nutritionally depleted to future feedings were in
properso. About 2 weeks post procedure, role
developed a probabe small bound abstruction t
frequent emotion. She developed P(b) (6) in t resp. failure.

B.E. Relevant Tostallaboratory Data, Including Dates (continued) A repeat islandson on 11/24 showed no siejes of recurent infections and she had no further dividea.

B.7. Other Relevant History, including Preexisting Medical Conditions (e.g., eliergies, race, pregnancy, amoking and alcohol use, hepalic/renal dysfunction, etc.) (continued)

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Individual Case Safety Report Parm Approved: OMB No. 0910-0201, Expires: 8/30/2015 Sep PKA setement on reverse. iRY reporting of sduct problems and Triege unit sequence # use errors e 1 of 3/ PATIENT INFORMATION Dose or Amount 1 time via extension to become Fomale 78 HO 73 Male Dates of Use (if unknown, give duration) from to (or best estimate) B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR 5. Event Absted After Use Stopped or Dose Reduced? #1 Yes No Docen 12/16/2015 . MAdverse Event Product Problem (e.g., delects/mellunctions) 82 Yes No Seesn Product Use Error Problem with Different Manufacturer of Same Medicine 2. Outcomes Attributed to Adverse Event (Check all that apply) 4. Diagnosis or Reason for Use (Indication) 8. Event Resposared After Reintreduction? Diff Death: Disability or Permanent Damage #1 Yes No Boos Life-Unrapherting Congenital Anomaly/Birth Defect #2 Yos No Poesn's Hospitalization - kildel or protonged Other Gerious (Important Medica) Events)
Required intervention to Prevent Permanent Impalment/Damage (Devices) (b)(6)Iretion Date 6/19/16 9. NDC # or Unique ID 1/2 3. Date of Event (mm/dd/yyy) 4. Date of this Report (mm/dd/yyy) 12/20/2015 13
5. Describe Event, Problem or Product Use Error E. SUSPECT MEDICAL DEVICE 12/23/15 1. Brand Nervis Pt armitter à sevene C-diff colitis, frester with Fegyl, HAMOMYUM THER were stoppers 24° et receive Fecul 2. Common Davise Name CTU 3. Manufacturer Name, City and State microbata transplant 12/16/15. improvios
O/L (b) (6) Reasonit (b) (6) with DEC 24 2015 4. Model # 5. Operator of Device ABP pain, fever, hypotension Health Professional Lay User/Petient Catalog # Expiration Date (mm/dd/yyyy) Other; 6. Relevant Tests/Laboratory Data, Including Dates Unique Identifier (UDI) d Berial S (b) (6) ct sim - significent coldic were 36.k(b) (6) were 11 (b) (6) 8. In this a dimplo-use Device that was Page Yes No 9. If Yas to Hom No. 0, Enter 7. Other Rejevant History, including Pressisting Medical Conditions (e.g., allergies, rece, preprieto, smoking and alcohol use, liverkidney problems, etc.) F. OTHER (CONCOMITANT) MEDICAL PRODUCTS the of CAS, DM & gastnopanesis, Product names and therapy dates (exclude treat send monthineny NA G. PRODUCT AVAILABILITY Product Available for Evaluation? (Do not send product to FDA) Yes Returned to Manufacturer on: (mm/dd/yyyy) D. SUSPECT PRODUCT(S) A: Name, Strength, Manufacturer (Imm product labol) Strength: Feed muchoboth prefection Manufacture: Open Brains Physician YES No Manufacturor 2 Name: Deer Facility 5. If you do NOT want your Identity died Strangth: to the manufacturer, place on "X" in this bex: Distributor/Importer Submission of a raport does not constitute an admission that medical personnel or the product caused or contributed to the event. FORM FDA 3500 (2/13)

> DSS DEC 9.4 2015

Inc	livi	dual	Case	Safety	Report	
		IOHARIAR		INKIR STANJAS	18/18/10/19/19	TE E BIR

FORM FDA' 3800 (2/13)

TARY reporting of

(b) (6) >> 18003320178 CBER

Form Appressed: DAIS No. UP10-0201, Expires: 6/30/2015 Spg PRA statement on reverse. 11905619-01-00-01 DA WEF WARE hun smeldard innband 1031853 product use arrors The FDA Safety Information and Page 1 of 3 Adverse Event Reporting Program A PAHENT INFORMATION Dese or Amount Frequency 250 cc via colunosupi E Pensie (b)(6)or 6858mg ☐ Mele Detos et Uso (If unknown, give duration) haroko for bost estimate) S. Event Abated After Use Stopped or Dese Reduced? B. ADVERSE EVENT, PRODUCT PROBLEM OF Stopped or Dess T 1 247 1. Adverso Evem [] Product Problem (e.g., defectshaftenchina) WE YES NO DECOUNT Product Use Error D Problem with Different Manufacturer of Same Medicine 6. Diagnosis or Renson for Use (Indication) 2. Outcomes Attributed to Adverse Event (Check at that apply) A. Event Respressed Alte Memoration Death Disability or Persumon Domage (ratte/cld/yyyy) Life-threatening Congenital Anomuly/Birth Deleci ME DAM DIP Abby 7. Explication Date Prospitalization - mittel or prolonged Oper Serious (Impurtant Medical Events) (b)(6)9. NOC # or Unlaun B Required intervention to Prevent Permanent Impairment/Damage (Devices) 3. Date of Event Inmediancy 17 19 2015 5. Describe Event, Problem or SUSPICT MEDICAL DEVICE 1. Brand Warns Fever P Fecal Transplant. 2. Common Device M 2b. Procode TYPE OR USE BLACK INK 3. Manufacturer Name, City and State 6. Operator of Davice LARD 4. Mestel S Health Professional Expiration Date (mm/dd/yyyy) Lay UsorPutient Catalog II Other, 6. Rolevest Teste/Leberatory Data, Including Dolero Unique Islantinor (UDD# Geriol # CTU 8 B Implanted, Give Date (marketyyy) 7. Explanted, Give Date (marketyyy) 2105 8 - MAL IAN -8 2016 8. Is this a Bingle-use Device that was Reprosposed and Roused on a Patient? DYD DNO Mo 5. If Yes to now Me. I, Evier Home and Addition of Reprocessor 7. Other Relevant History, including Pressisting Medical Conditions (e.g., obscious, case, pressency, amplians and etcahol use, liverlidiney practicals, etc.) OTHER (L'INCOMITANT) MUDICAL PRODUCT Multiple Mystoma Product names and therapy dates (publish tealment of event) C. REPOSTER (See sumbitude any section on both PROBUCT AVAILABILITY Product Available for Evaluation? (Do not send product to PDA) You No Relumed to Manufacturer on S (MANY OCH PROPERTY) SURBLY CO PRODUCTION A. Alpino, Strength, Monutectures from product Misch 201 m Home: Open Blome Manufacturer Fecal Microla ota Preparation 2. Heang Protoceissel? 3 (16 st) a unbendle & Marviconurer Yos No 8. I you do NOT want your Momity disch Sirength: to the manufacturer, place an oxu in tak sex: Distributorfimpories Manufactures: Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



12105458-01-00-01

reporting of problems and trors

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 See PRA statement on reverse.

	COD I TO TOLLION ON TOTAL
	FDA USE ONLY
Triage unit sequence #	639170
FDA Rec. Date	
¥	

Note: For date prompts of "dd-mmm-yyyy" please use 2	-digit day, 3-letter month	3. Dose or Amount	Frequency	Route
abbreviation, and 4-digit year; for example, 01-Jul-2015.		#1 250 cc	once	sigmoidoscopy
A. PATIENT INFORMATION				
1. Patient identifier 2. Age Year(s) Month (b) (6)		#2 250 cc	once	enema
Week(s) Days(		- Detro of Hon /Fram/To	dereach) (Mustersum	9. Event Abated After Use
or Date of Birth (e.g., 08 Feb 1925	TY Male	4. Dates of Use (From/To	stimate) (dd-mmm-yyyy)	Stopped or Dose Reduced?
In Confidence	□ kg	#1 01/21/2016		#1 Yes No Doesn't
5.a. Ethnicity (Check 5.b. Race (Check all that app	••	#2 01/28/2016		apply
single best enswer) Asian American Ind		5. Diagnosis or Reason i	for Use (indication)	#2 Yes No Doesn't
Disck of Afficial Afficial		#1 severe C diffi	cile infection	apply
☑ Not Hispanic/Latino ☐ Native Hawaiian or Other	Pacific Islander			10. Event Reappeared After
B. ADVERSE EVENT, PRODUCT PROBLE	€M	#2		Reintroduction?
1. Check all that apply				#1 Yes No Doesn't
Adverse Event Product Problem (e.g., def	ects/malfunctions)	6. is the Product Compounded?	7. Is the Product Over- the-Counter?	apply
Product Use Error Problem with Different Ma	nufacturer of Same Medicine	0		#2 Yes No Doesn't
2. Outcome Attributed to Adverse Event (Check all the	The state of the s	1 100 23.110		apply
	) (6)	#2 Yes No	#2 Yes 🖾 No	
	ty or Permanent Damage	8. Expiration Date (dd-mi		
	nital Anomaly/Birth Defects	#1	#2	
Other Serious (Important Medical Events)		E. SUSPECT MEDI	CAL DEVICE	<b>建设设置的</b>
Required Intervention to Prevent Permanent Impairm	ent/Damage (Devices)	1. Brand Name		
3. Date of Event (dd-mmm-yyyy) 4. Date of this	Report (dd-mmm-yyyy)			
$\underbrace{\begin{array}{c c}04-Feb-2016\end{array}}$	Feb - 2016	2. Common Device Name	CTI	2b. Procode
5. Describe Event, Problem or Product Use Error	d and atrial			
Conter serious (important Medical Events)  Required Intervention to Prevent Permanent Impairm  3. Date of Event (dd-mmm-yyyy)  4. Date of this  0 4 - Feb - 2016  5. Describe Event, Problem or Product Use Error 86 y/o M with glaucoma/legally him fibrillation, who was admitted (b)	(6) with severe,	3. Manufacturer Name, C	tty and StREB 22	2016
complicated C difficile colitis. He	underwent fecal	11	-	
transplant x 2 (1/21/16 and 01/28/1 improved. Stools became formed. On			T	
declined with hypotension, hypoxemi (b) (6) Blood culture grew gram n		4. Model #	Lot #	5. Operator of Device
	egative rods.	Catalog #	Expiration Date (de	Beeforeignal
6. Relevant Tests/Laboratory Data, Including Dates		Catalog #		I by Hear/Detient
6. Relevant Tests/Laboratory Data, Including Dates		Serial #	Unique Identifier (	Other
Blood culture 02/03/2016: Klebsiell	a pneumonia		Cinque taemaner (	
		6. If Implanted, Give Date	(dd-mmm-yyyy) 7. If Ex	planted, Give Date (dd-mmm-yyyy)
		8. Is this a single-use de		
7. Other Relevant History, including Preexisting Medic		reprocessed and reus	ed on a patient?	Yes No
allergies, pregnancy, smoking and alcohol use, liver/kic atrial fibrillation, hypertension,		9. If Yes to Item 8, Enter	Name and Address of R	eprocessor
	,			
		F. OTHER (CONCO	MITANT) MEDICAL	PRODUCTS
C. PRODUCT AVAILABILITY	Miles Markey and I have a server and	Product names and there		THE RESERVE AND ACT OF THE PERSON NAMED IN
2. Product Available for Evaluation? (Do not send prod	urd to EDA)	5	••	•
Yes No Returned to Manufacturer				and the second
		G. REPORTER (See	e confidentiality sed	ion on hady
D. SUSPECT PRODUCTS	96年 (1974年) (1974年)	1. Name and Address		
1 Name, Manufacturer/Compounder, Strength (from pi	roduct label)			01
#1)- Name and Strength	#1 - NDC # or Unique ID			6
Donor stool	(b) (6)			6)
#1 - Manufacturer/Compounder	#1 - Lot #			0
Openbiome DCC				
#2 - Name and Strength	#2 - NDC # or Unique ID	2. Health Professional?	3. Occupation	4. Also Reported to:
Donor stool FFB 2 2 2016		Yes No	Physician	Manufacturer/
#2 - Manufacturer/Compounder	42 101#	5. If you do NOT want you		Compounder  User Facility
Openbiome	(b) (6)	to the manufacturer, plea		Distributor/Importer

Individual	Case	Salety	Keboir	
	MINIMA		1001001001001	1 111
				H
dis ibmanahabiteiri	RIBITATION	I ME I O AL BRIDGE	INTERNO : CALIFIAIR ;	8 Iria

12166980-01-00-01

ARY reporting of court problems and reverse.

See PRA statement on reverse.

FDA USE ONLY

Triage unit sequence #

FDA Rec. Date

•		<i>i</i> 1		J A O P A P
Note: For date prompts of "dd-mmm-yyyy" please use 2-	digit day, 3-letter month	3. Dose or Amount	Frequency	Route
abbreviation, and 4-digit year; for example, 01-Jul-2015,		#1 250 cc		via sigmoidoscopy
A. PATIENT INFORMATION	3. Sex 4. Weigh	#2 250 cc	=======================================	via sigmoidoscopy
(b) (6) 2. Age Year(s) Month	(5)	#2 250 cc		Via Sigmordoscopy
or Date of Birth (e.g., 08 Feb 1925	,	4. Dates of Use (From/To	for each) (If unknown,	9. Event Abated After Use
In Confidence	Male kg	give duration, or best e #1 06/jan/2016	stimate) (dd-mmm-yyyy)	Stopped or Dose Reduced?  #1 Yes No Doesn't
5.a. Ethnicity (Check 5.b. Race (Check all that app	(y)	#2 11/jan/2016		apply
single best enswer) Asian American Ind		5. Diagnosis or Reason	for Use (indication)	#2 Yes No Doesn't
☐ Hispanic/Latino ☐ Black or African American ☐ Not Hispanic/Latino ☐ Mative Hawaiian or Other		#1 severe, refrac	tory C difficile	apply
		#2		10. Event Reappeared After Reintroduction?
B. ADVERSE EVENT, PRODUCT PROBLE  1. Check all that apply	TYB	F2		#1 Yes No Doesn't
Adverse Event Product Problem (e.g., def	ects/malfunctions)	6. Is the Product	7. Is the Product Over-	
Product Use Error Problem with Different Ma	nufacturer of Same Medic	ne Compounded?	#1 Yes No	#2 Yes No Doesn't
2. Outcome Attributed to Adverse Event (Check all tha	f apolivi (6)	0.00		apply
Dean include date (od-lining-yyyy).	y or Permanent Damage	#2 Yes No		<u> </u>
	ital Anomaly/Birth Defects	#1	#2	
Other Serious (Important Medical Events)		E. SUSPECT MEDI		
Required Intervention to Prevent Permanent Impairm	enVDamage (Devices)	1. Brand Name	3000	
7.72.	Report (dd-mmm-yyyy)			
	Feb - 2016	2. Common Device Nam	ė	2b. Procode
5. Describe Event, Problem or Product Use Error Patient will multiple comorbidities	: severe C	3. Manufacturer Name, (	Sty and State	
difficile infection. Treated with F	MT. Though the C	S. Manufacturer Ivanie,	A A	1AR - 9 2016
difficile improved, he continued to cardiac and respiratory issues as w	suffer from		U	lift a reu
neurologically from recent hemorrha	gic stroke. Was	4. Model#	Lot #	5. Operator of Device
transferred to hospice and expired	on (D) (O)			Health Professional
	<b>医关节的 的现在分词</b> 电线	Catalog #	Expiration Date (dd	Lay User/Patient
6. Relevant Tests/Laboratory Data, Including Dates		Serial #	Unique identifier (I	Other
was 36,000, C diff + stools Abdomi colon (at admission (b) (6)	nal CT-fluid fills	d		
		6. If Implanted, Give Dat		planted, Give Date (dd-mmm-yyyy)
Sigmoidoscopy on 0i/11/16-mild pseu	domenuranes	8. Is this a single-use de		
7. Other Relovant History, Including Preexisting Medi-	cal Conditions (e.g.,	reprocessed and reus	sed on a patient?	Yes No
allergies pregnancy, smoking and alcohol use, liver/kik	iney problems, etc.)	9. If Yes to Item 8, Enter	Name and Address of Re	sprocessor
hemorrhagic CVA, PEG tube placement replacement/mechanical valve, myelo	, mitral valve dysplastic syndrom	ie		
•				
		F. OTHER (CONC	DMITANT) MEDICAL	PRODUCTS
C. PRODUCT AVAILABILITY	11 11 2 1 12	Product names and the	rapy dates (Exclude treatm	nent of event)
2. Product Available for Evaluation? (Do not send prod				es e
Yes No Returned to Manufacturer		G. REPORTER (Se	e confidentiality sed	tion on back)
D. SUSPECT PRODUCTS		1. Name and Address		
1. Name, Manufacturer/Compounder, Strength (from p	roduct label)		- 1	01
#1 - Name and Strength	#1 - NDC # or Unique ID			h
FMT				6)
#1 - Manufacturer/Compounder	#1 - Lot # (b) (6)			
Openbiome	#2 – NDC # or Unique IC	2. Health Professional?	3. Occupation	4. Also Reported to:
#2 - Name and Strength FMT MAR 0 9 2016	#2 - NDC # of Offique IL	Yes No	physician	Manufacturer/ Compounder
#2 – Manufacturer/Compounder	#2 - 1 ot #	5. If you do NOT want y	our identity disclosed	User Facility
#2 — Mailulactulei/Odinpodidei	(b) (6)	to the manufacturer, ple	ease mark this box:	☐ Distributor/Importer

FORM FDA 3500 (10/15)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CBER

		Form Approved: OMB	No. 0910-0291, Expires: 6/30/2015 See PRA statement on reverse.
12203638-01-00-01	ARY reporting of oduct problems and	FDA	USEONLY
	ct use errors	Triage unit sequence #	maning allegant
The FDA Safety Information and Adverse Event Reporting Program	age 1 of 3!	4449	75
A. PATIENT INFORMATION	2. Dose or Amount	Frequency R	oute
1. Patient Identifier 2. Age at Time of Event or Date of Birth:	1b #1 30 nel	<u> </u>	H GT
In confidence  B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR Check at that apply:	3. Dates of Use (If unknow for best estimate)		5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't
MAdverse Event Product Problem (e.g., defects/mallunctions) Product Use Error Problem with Different Manufacturer of Same Med	#2 4. Diagnosis or Reason for	or Use (Indication)	#2 Yes No Doesn't Apply
2. Outcomes Attributed to Adverse Event OTHER (Check ell that apply)  Death: Disability or Permanent Damage	"c-diff		8. Event Reappeared After Reintroduction? #1 Yes No Doesn't
(mm/dd/yyyy)  Life-threatening Congenital Anomaly/Birth Defect	#2		#2 Tyes TNo Doesn't
☐ Hospitalization - initial or prolonged ☐ Other Senous (Important Medical Ev ☐ Required Intervention to Prevent Permanent Imperment/Damage (Devices)		Expiration Date	9. NDC # or Unique ID
3. Date of Event (mm/dd/yyyy) 3. UN 2016 4. Date of this Report (mm/dd/yyyy)	E. SUSPECT MEDI		
5. Describe Event, Problem or Product Use Error	1. Brand Name	1+	*
- vomiting 7 hours after 7 MT; gremedica with PPi and ondansetvom	2. Common Device Name		2b. Procode
after FMT; premedica	3. Manufecturer Name, C	ity and State	
with pri and	4. Model #	Lot #	5. Operator of Device
ondansetvon	Catalog #	Expiration Data (mm	/dd/yyyy) Ley User/Patient Other:
Relevant Tests/Laboratory Data, Including Dates	Serial #	Unique identifier (UI	
cm H/+ DSS	6. If Implanted, Give Date		lanted, Give Date (mm/dd/yyyy) d and Reused on a Patient?
MAR 2 2 2016 MAR 2 2 2	Yes No  9. If Yes to Item No. 8, Ent	or Name and Address of Re	
7. Other Relevant History, Including Preexisting Medical Conditions (e.g., aftergles, race, pregnancy, smoking and alcohol use, liver/kidney problems, sto			
== vo Limale, with	F. OTHER (CONC	OMITANT) MEDICAL rapy dates (exclude treetme	
recurrent c-oliff, who developed SELF-LIMITED Vonuting, 7 h after FMT	H/		
developed SELF-LIMITED	G. REPORTER (Se	e confidentiality secti	on on back)
C. PRODUCT AVAILABILITY		1-1	101
Product Available for Evaluation? (Do not send product to FDA)  Yes No Returned to Manufacturer on: (mm/dd/yyyy)			Inl
D. SUSPECT (PRODUCTI(S)  1. Nème, Strongth, Manufacturer (from product let #1 Name: FMT 60 # Ke (b) (6)		9	101
strength: OPEN BIOME	∠. Heäim Fibiassinisit	PHYSICI AN	Manufacturer
#2 Name: Strength:	5. If you do NOT want yo		User Facility  Distributor/Importer



Health 1 Report Y reporting of uct problems and

ase errors

Form Approved: OMB No. 0910-0291, Expires: 09/30/2018 See PRA statement on reverse.

	FDA USE ONLY	
riage unit equence #	1647818	
DA Rec.		
ate		_
	Pouto	-

## The FDA Safety Information and

Adverse Event	Reporting Program	1				Date	
Note: For date prom	ante of "dd-mmm-vavy" th	ease use 2-digit day, 3-letter	month	3. [	Dose or Amount	Frequency	Route
	digit year, for example, 0		1	#1	30 (6) (4)	once	Disl
A. PATIENT I			STORY MES	(  "			
1. Patient Identifier		[] Mandh(n)   a Cons	4. Weight	11 !			
(b) (6)			73	#2	1 1		
(0) (0)	☐ Week(s)	Day(s) Femal					
	or Data of Birth (20	08 Feb 1925)	al 🗌	1 5	ten of the (From/To	for each) (if unknown,	9. Event Abated After Use
	(b) (b)	✓ Male	✓ kg	giv	e duration, or best e	stimate) (dd-mmm-yyyy)	Stopped or Dose Reduced?
In Confidence				#1 2	4-Mar-2016 - 24-Ma	r-2016	#1 Yes No Doesn't
5.a.Ethnicity (Che		all that apply)		#2		141	— — Doesn't
single best answer	Asian 🗀	American Indian or Alaskan	Native	5. Dia	gnosis or Reason I	or Use (indication)	#2 Yes No apply
Hispanic/Latin	Black or Afri	can American Wh	nite	#1 *	ecurrent C. diffic	ile colitis	10.Event Reappeared After
☑ Not Hispanic/				"			Reintroduction?
E	L Hazre Ham	aiian or Other Pacific Islander	NAME OF STREET	#2			#1 Yes No Doesn't
B. ADVERSE	EVENT, PRODUCT	PROBLEM		l I			- Descrip
1. Check all that a	apply				he Product	7. Is the Product	#2 Yes No apply
✓ Adverse Even	nt Product Probl	em (e.g., defects/malfunction	s)	Co	mpounded?	Over-the-Counter?	
Product Use I	Green Problem with f	Different Manufacturer of Sa	ame Wedicine	#1	Yes No	#1 Yes No	4
	_			#2	Yes No	#2 Yes No	
2. Outcome Attrib	outed to Adverse Event	(Check all that apply)		B. Exp	iration Date (dd-mn	nm-yyyy) #1 13-Apr-201	6 #2
	e date (dd-mmm-yyyy): _			11 '	SUSPECT MED	E A SON LE CHESTANTE DE COMPANI	A SURVEY AND THE STATE OF THE ABOUT AND ASSESSED.
		Disability or Permanen	t Damage	Company of the last of the las	and Name		
Life-threatenin	ng n - initial or prolonged	Congenital Anomaly/Bi	rth Defects	1, 51	allu Nælle		
	(Important Medical Even	L		11		Cl	ru -
Other Serious Required Inte 3. Date of Event ( 01-Apr-2016 5. Describe Event See addition	overtion to Prevent Perm	anent Impairment/Damage (D	Devices)	2 60	mmon Device Name	A	2b. Procode
Tredailed line		4. Date of this Report (dd-r		1		ADD -	5 2016
3. Date of Event (	dd-mmm-yyyy)	4. Date of this Report (DO-	min-yyyy)	3. Ma	nufacturer Name, C	ity and State	
01-Apr-2016	#1 × .	04-Apr-2016		11			
	Duchlam or Droduct II	ro Error		11			
5. Describe Event	, Problem or Product Us hal page(s) for c	omplete text		4. Mc	del#	Lot#	5. Operator of Device
See addition	al page(s) for c	Omplete text.		11			1
				11			Health Professional
6. Relevant Tests/				Cata	log#	Expiration Date (dd-	-mmm-yyyy) Lay User/Patient
6. Relevant Tests/	Laboratory Data, Includ	ing Dates					Other:
				11			Li Ollies.
				Ser	al#	Unique Identifier (U	JDI) #
7 Other Pelevent	E .					1	
7 Other Relevant	History Including Pree:	dsting Medical Conditions	(e.g.,	11			
allergies, pregna	ancy, smoking and alcoho	use, liver/klaney problems, t	etc.)	6 1(1	mplanted, Give Dat	e (dd-mmm-yyyy) 7. If Es	xplanted, Give Date (dd-mmm-yyyy)
See additions	al page(s) for co	mplete text.					
				8 15	this a single-use de	vice that was	□ Voc □ Na
				re	processed and reus	sed on a patient?	Yes No
C. PRODUCT A	AVAILABILITY	According to the Control of		9. If	res to Item 8, Enter N	lame and Address of Repro	ocessor
2 Product Availab	ble for Evaluation?(Do n	ol send product to FDA)					
☐ Yes 🗸	No Returned to Ma	anufacturer on:(dd-mmn	n-yyyy)	3	OTHER (CONC	OMITANT) MEDICA	L PRODUCTS
D. SUSPECT	PRODUCTS			Prod	luct names and the	rapy dates (Exclude treatm	nent of event)
1 Name Manufact	turer/Compounder, Stre	ngth (from product label)					0 - 10
#1 - Name, Manurac	anoth	#1 - NDC # or Unique	e ID			ee confidentiality section	on back)
FMT (b) (	4)	(b) (C)		1 N:	ama and Address		
(~) (	1. 1.	(D)(D)					101
		, , , ,					
				1			(6)
#1 - Manufacturer/	Compounder	#1- Lot #					
OpenBiome							
	- 4	#2 - NDC # or Unique	ID	- 585			
#2 - Name and Str	ength	#Z - NDC # or Unique					
				2. H	ealth Professional?	3. Occupation	4. Also Reported to:
					√Yes No	Medical Doctor	[7] Manufacturer/
#2 - Manufacturer/	Compounder	#2- Lot #		┨ '		(Physician)	Compounder
	W 0 0 0 0	4		5. If	you do NOT want y	our identity disclosed	User Facility
,	70: 24 (4)	-		to	the manufacturer,	please mark this box: [	Distributor/Importer
				ال			
1	- F 2 7 15 1			<del>-</del>	and the state of the same of		or contributed to the event

FORM FDA 3500 (10/15) APR 5 2016

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



12240892-01-00-02

647818

The patient received an OmenBiome FMT (b)(4) fecal transplant on 3/24/2016. He was kept in the hospital until (b)(6). His diarrhea resolved completely prior to discharge. He was afebrile and without abdominal pain/tenderness at discharge. In addition, he had no evidence of leukocytosis or renal dysfunction during this hospitalization. Following discharge, the diarrhea recurred and he developed severe abdominal pain. He returned to the hospital on (b)(6) with recurrent C. diff, pancolitis and colonic perforation as well as secondary psoas abscess complicated by necrotizing fasciitis. He underwent exploratory laparotomy, subtotal colectomy with end ileostomy and debridement of the left thigh wound on (b)(6) He's currently in the Intensive Care Unit on pressors and intubated. He is making minimal urine output and may require dialysis.

B.6. Relevant Tests/Laboratory Data, Including Dates (continued)

B.7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) (continued)

(b) (6)

chronic hepatitis B (on (b) (6), presumed disseminated MAC, latent TB infection, prior CMV viremia and stage 4 DLBCL (diagnosed in 8/2015, s/p 3 cycles of R-EPOCH most recently in 1/2016, in complete remission in 11/2015 + high-dose methotrexate). He received a fecal transplant in the setting of his third episode of C. difficile colitis.

F. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Receipt No: RCT-93891 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2017-69194 | Department: CBER | RCT No.: RCT-93891 | CTU Triage Date: 01-11-2017 | AER #: 141518 19 | Total Pages: 4

All dates displayed in the report are in EST(GMT-05:00) time zone

Company Unit	Basic Details	15.70	<b>2.</b>						
Priority Routine  FDA Received Date  O1-Nov-2017  CTU Triage Date  Report Type  Assign To  User/  COPER (CDER-OSE-RSS-CTU@ida.hhs.gov) (E2B)  Contains  Coper First Name  Case First Name  Last Name  Email Address  Phone  Case First Name  Patient Inferiority  Age 38 Year(s)  Date of Birth  Sex Female  Weight  Ethnicity (Check single best answer)  Rece (Check all that apply)  Adverse Event  Product Use Fore Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore  Product Use Fore Product Problem (e.g., defectionally)  Check all that apply)  Date of Adverse Event Product Use Fore Product Use Fo	Company Unit	CDER-CTU Originating Account FAERS							
FDA Received Date	Source Medium	MWO (Drug) Source Form Type E2B XML 3500							
CTU Triage Date  Report Type	Priority	Routine							
Report Type Assign To User User/Group Forward to Department    CDER (CDER-OSE-RSS-CTU@(da.hhs.gov) (E2B)	FDA Received Date	01-Nov-2017	CTU Received Date	01-Nov-2017					
Assign To User/Group  Forward to Department  Case   First Name   Last Name   Email Address   Phone   Reporter	CTU Triage Date								
Control	Report Type	Spontaneous	Report Classification	Drug					
Forward to Department  Cober (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)  First Name  Last Name  Email Address  Phone  Patient Información  Age  38 Year(s)  Date of Birth  Sex  Female  Weight  Ethnicity (Check single best anawor)  Race (Check all that apply)  Asian  Amenican Indian or Alaskan Native  Black or African American  White  Native Howarian or Other Pacific Islander  Check all that apply  Death  Lile-streatening Hospitalization - Initial or prolinged Other Serious (Important Medical Events) Deasth Lile-streatening Hospitalization - Initial or prolinged Other Serious (Important Medical Events) Deasth Death Death Date of Death  Date of Death Date of Event Date of this Report  Other Pacific Islander  Product Poster or Same Important Impairment/Damage (Devices)	Assign To	User							
Contest:  Case   First Name   Last Name   Email Address   Phone      Age   38 Year(s)	User/Group								
Case Reporter  Case First Name Last Name Email Address Phone    Case Reporter   Case Reporter   Case   Case	Forward to Department	CDER (CDER-OS	SE-RSS-CTI (@fda hhs gov) (F2B)						
Case Reporter   First Name		E OBEN (OBEN OC	(LLD)						
Coopenies   Coop	Contact								
Date of Death   Date of Death   Date of Event   Date of Intervent   Date of Death   Date of Event   Date of Death   Date of Event   Date of Death   Date of Event   Date of Interventic   Date of Interv	Case First Name	Last Name	Email Address	Phone					
A PATIENT INFORMATION  Patient Identifier (in Confidence) (b) (6)  Age 38 Year(s)  Date of Birth			/b\ /C\						
Patient Identifier (In Confidence)  Age 38 Year(s)  Date of Birth  Sex Female  Weight 67.1 kg(s)  Ethnicity (Check single best answer)  Race (Check all that apply)  Asian  American Indian or Alaskan Native  Black or African American  White  Native Hawaiian or Other Pacific Islander   B. ADVERSE EVENT, PRODUCT PROBLEW  Check all that apply  Adverse Event  Product Problem (e.g., defects/malfunctions)  Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Death  Life-threatening  Hospitalization - initial or prolonged  Other Serious (Important Medical Events)  Disability or Permanent Damage  Congenital Anomaly/Birth Defects  Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death  Date of Event  28-Oct-2017  Date of this Report  O1-Nov-2017			(n) (a)						
Age 38 Year(s)  Date of Birth  Sex Female  Weight 67.1 kg(s)  Ethnicity (Check single best answer)  Race (Check all that apply)  Asian American Indian or Alaskan Native Black or African American White Notive Hawaiian or Other Pacific Islander   **DADVERSE EVENT, PRODUCT PROBLEM*  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Protect Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Adverse Event (Check all that apply)  Date of Death  Date of Death  Date of Event Date of Event Date of Event Date of Inative Adverse Server (28-Oct-2017 Date of Inative Adverse (18-Oct-2017 Date of Inative Adver	A. PATIENT INFORMATION								
Date of Birth  Sex Female  Weight 67.1 kg(s)  Ethnicity (Check single best answer)  Race (Check all that apply)  Asian  American Indian or Alaskan Native  Black or African American  White  Native Hawaiian or Other Pacific Islander  BADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Adverse Event  Product Use Error  Product Problem (e.g., defects/malfunctions)  Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Hospitalization - initial or prolonged  Other Serious (Important Medical Events)  Disability or Permanent Damage  Congenital Anomaly/Birth Defects  Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death  Date of Event  28-Oct-2017  Date of this Report	Patient Identifier (In Confidence)	(b) (6)							
Sex   Female	Age	38 Year(s)							
Weight 67.1 kg(s)  Ethnicity (Check single best answer)  Race (Check all that apply)  Asian American Indian or Alaskan Native Black or African American White Native Hawaiian or Other Pacific Islander  B. ADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Life-threatening Life-threatening Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event Date of this Report  01-Nov-2017	Date of Birth ,								
Ethnicity (Check single best answer)  Race (Check all that apply)  Asian American Indian or Alaskan Native Black or African American White Notive Hawsiian or Other Pacific Islander  B. ADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event Date of this Report  01-Nov-2017	Sex	Female							
answer)  Race (Check all that apply)  Asian American Indian or Alaskan Native Black or African American White Native Hawaiian or Other Pacific Islander  B. ADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event Date of this Report  01-Nov-2017	Weight	67.1 kg(s)							
American Indian or Alaskan Native   Black or African American   White   Native Hawalian or Other Pacific Islander		Hispanic/Latino							
B. ADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event  Date of Event  O1-Nov-2017	Race (Check all that apply)	American Indian or Alaskan Native							
B. ADVERSE EVENT, PRODUCT PROBLEM  Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply) Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event Date of this Report  01-Nov-2017		White							
Check all that apply  Adverse Event Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply)  Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death  Date of Event  28-Oct-2017  Date of this Report  01-Nov-2017		Native Hawaiian or Othe	r Pacific Islander						
Product Use Error Product Problem (e.g., defects/malfunctions) Problem with Different Manufacturer of Same Medicine  Outcome Attributed to Adverse Event (Check all that apply) Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death  Date of Event Date of this Report  01-Nov-2017	B. ADVERSE EVENT, PRODUC	T PROBLEM							
Event (Check all that apply)  Life-threatening Hospitalization - initial or prolonged Other Serious (Important Medical Events) Disability or Permanent Damage Congenital Anomaly/Birth Defects Required Intervention to Prevent Permanent Impairment/Damage (Devices)  Date of Death Date of Event 28-Oct-2017  Date of this Report  01-Nov-2017	Check all that apply	Product Use Error Product Problem (e.g., d							
Date of Event         28-Oct-2017           Date of this Report         01-Nov-2017	Event (Check all that apply)	Death Life-threatening Hospitalization - initial or Other Serious (Important Disability or Permanent I Congenital Anomaly/Birtl	Life-threatening  Hospitalization - initial or prolonged  Other Serious (Important Medical Events)  Disability or Permanent Damage  Congenital Anomaly/Birth Defects						
Date of this Report 01-Nov-2017									
		5 N 2 C 50 H 1 1 1 2 2 4 C 5 C 5 C 5 C 5 C 5 C 5 C 5 C 5 C 5 C							

Receipt No: RCT-93891 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2017-69194 | Department: CBER | RCT No.: RCT-93891 | CTU Triage Date: 01-11-2017 | AER #: 141518 19 | Total Pages: 4

	Describe Event, Problem, or Prod after Fecal transplant.	Juct Use Error: Patie	nt reports abdominal discomf	ort, bloating, and blood per rectum 10	) days
13	elevant Tests/Laboratory Data	Inclination Dailed			
h 3	Sevent 1998/1999/telly Settle	Tostering Server			
0	ther Relevant History, Including	preexisting Med	feal Conditions		Profession of the Parket
	Participant has pre-existing chron	The same and the s	The state of the s		
C	PRODUCT AVAILABILITY				
	Product Available for Evaluation? (Do not send product to FDA)	No			
	Returned to Manufacturer on				
D.	SUSPECT PRODUCTS				र्जी
	Product Name	Fecal Transplant			
	Strength		If Other		
	Manufacturer/Compounder				-
	NDC# or Unique ID				
	Lot Number .				
	Dose or Amount		If Other		
	Frequency	Other	If Other	once	
	Route	Rectal	If Other		
	Therapy Start Date	18-Oct-2017			
	Therapy End Date	18-Oct-2017			
	Therapy Duration		If Other		
	Diagnosis or Reason for Use (indication)	Chronic Pouchitis			
	Is the Product Compounded?		*		24
	Is the Product Over-the-Counter?				
	Expiration Date	18-Oct-2017			381
	Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply		*	
	Event Reappeared after Reintroduction ?	Doesn't Apply	e	9	
Ē,	SUSPECT MEDICAL DEVICE				
	Brand Name				
	Common Device Name				
	Procode				
	Manufacturer Name				

Generated by: SYSTEM Generated on:

01-Nov-2017 14:46:05

Receipt No: RCT-93891 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2017-69194 | Department: CBER | RCT No.: RCT-93891 | CTU Triage Date: 01-11-2017 | AER #: 141518 19 | Total Pages: 4

City			×	
State				
Model #				
Lot#				
Catalog #				
Expiration Date				
Serial #				
Unique Identifier (UDI) #				
Operator of Device	Health Professional  Lay User/Patient  Other			
Other				
If Implanted, Give Date				
If Explanted, Give Date		3		
Is this a single-use device that was reprocessed and reused or a patient?	n			
If Yes for the above field, Enter Name and Address of Reprocessor				
F. OTHER (CONCOMITANT) N CONCOMITANT MEDICAL PRO	MEDICAL PRODUCTS DUCT DESCRIPTION			
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PROPERTY OF THE CONCOMITANT) A Product Name  Strength	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) IN CONCOMITANT MEDICAL PROPERTY OF THER (CONCOMITANT) IN Product Name  Strength  Therapy Start Date  Therapy End Date	DUCT DESCRIPTION			1 of 1
F. OTHER (CONCOMITANT) IN CONCOMITANT MEDICAL PROPERTY (CONCOMITANT) IN Product Name  Strength  Therapy Start Date  Therapy End Date  G. REPORTER	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1
F. OTHER (CONCOMITANT) IN CONCOMITANT MEDICAL PROPERTY OF THER (CONCOMITANT) IN Product Name  Strength  Therapy Start Date  Therapy End Date  G. REPORTER  Last Name	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 07 1
F. OTHER (CONCOMITANT) IN CONCOMITANT MEDICAL PROPERTY (CONCOMITANT) IN Product Name  Strength  Therapy Start Date  Therapy End Date  G. REPORTER  Last Name  First Name	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1
F. OTHER (CONCOMITANT) IN CONCOMITANT MEDICAL PROPERTY OF THE CONCOMITANT) IN Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 07 1
F. OTHER (CONCOMITANT) N CONCOMITANT MEDICAL PRO  F. OTHER (CONCOMITANT) N Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City	DUCT DESCRIPTION	If Other		1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City State/Province/Region	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 07 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City State/Province/Region Country	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City State/Province/Region Country ZIP/Postal Code	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City State/Province/Region Country ZIP/Postal Code Phone	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1
F. OTHER (CONCOMITANT) A CONCOMITANT MEDICAL PRO F. OTHER (CONCOMITANT) A Product Name Strength Therapy Start Date Therapy End Date  G. REPORTER Last Name First Name Address City State/Province/Region Country ZIP/Postal Code	DUCT DESCRIPTION  MEDICAL PRODUCTS	If Other		1 of 1

FDA 3500 Form Receipt No: RCT-93891

CTU No.: FDA-CDER-CTU-2017-69194 | Department: CBER | RCT No.: RCT-93891 | CTU Triage Date: 01-11-2017 | AER #: 141518 19 | Total Pages: 4

Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
If you do NOT want your identity disclosed to the manufacturer, please mark this box:		

01-Nov-2017 14:46:05 Generated on:

Receipt No: RCT-105326 FDA 3500 Form

ΛII	dates o	dienlay	nd in	the re	nort ar	o in	EST	CMT	05·00)	time	7000
AII	uales (	uispiay	ea III	the re	port an	E 111	EOI	GIVII	-05.00)	ume	Zone

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Basic Det			Tarr		
Company		CDER-CTU		nating Account	FAERS
Source Me	edium	MWO (Drug)	Sour	ce Form Type	E2B XML 3500
Priority		Routine			
FDA Rece	ived Date	15-Dec-2017	СТИ	Received Date	15-Dec-2017
CTU Triag	e Date				
Report Typ	oe	Spontaneous	Repo	rt Classification	Drug
Assign To		User			
User/Group	р				
Forward to	Department	CDER (CDER-O	SE-RSS-CTI	J@fda.hhs.gov) (E2B)	
			1 1		
Contact					
Case	First Name	Last Name		Email Address	Phone
Reporter			/b\	(C)	
$\square$			(b)	(0)	
A DATIEN	NT INFORMATION				
		(b) (6)			
	Identifier (In Confidence)				
Age	D: 4L	38 Year(s)			
Date of	Birth	<u> </u>			
Sex		Female			
Weight		67.6 kg(s)			
Ethnicity answer)	y (Check single best	Hispanic/Latino			
Race (C	Check all that apply)	Asian			d a
		American Indian or Alas	skan Native		
		Black or African America	an		
		White			
		Native Hawaiian or Othe	er Pacific Island	ər	
B. ADVER	SE EVENT, PRODUC	TPROBLEM			
Check a	all that apply	Adverse Event			
		Product Use Error			8
		Product Problem (e.g., o	defects/malfunct	ions)	
		Problem with Different M			
Outcom	e Attributed to Adverse	Death			
Event (0	Check all that apply)	Life-threatening			
		Hospitalization - initial or	r prolonged		
		Other Serious (Importan		s)	
		Disability or Permanent			
		Congenital Anomaly/Birt			
				nent Impairment/Damage (Devi	ices)
Date of	Death				
Date of	Event	20-Nov-2017			
Date of t	this Report	15-Dec-2017			

Receipt No: RCT-105326 FDA 3500 Form

	Describe Event, Problem or Pro	educt Use Error			
	clinic during her follow up visit. F	Participant reports h	naving decreased energy and in	n increased nausea and stool frequency in infrequent appetite. Participant denies seeing curring since receiving the fecal transplant.	
100	Relevant Tests/Laboratory Data	i Including Date			
0	Other Relevant History, Includin	g Preexisting Me	edical Conditions		
	Participant is allergic to gadoliniu colitis associated pouchitis for wh	m containing comp nich this intervention	ounds, morphine, and Zofran. n was indicated.	She has been diagnosed with ulcerative	
C	. PRODUCT AVAILABILITY			Water water to the second of the sail file.	
	Product Available for Evaluation? (Do not send product to FDA)	No			
	Returned to Manufacturer on				
D	SUSPECT PRODUCTS			1 of 1	25.0
	Product Name	Fecal Microbiota			
	Strength		If Other		
	Manufacturer/Compounder		*		
	NDC# or Unique ID				
	Lot Number				
	Dose or Amount		If Other		
	Frequency	Other	If Other	Administered once	
	Route	Rectal	If Other		
	Therapy Start Date	18-Oct-2017			
	Therapy End Date	18-Oct-2017			
	Therapy Duration		If Other .		
	Diagnosis or Reason for Use (indication)	Ulcerative colitis a	associated pouchitis		
	Is the Product Compounded?				
	Is the Product Over-the-Counter?				
	Expiration Date				
	Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply	0		
	Event Reappeared after Reintroduction ?	Doesn't Apply			
On B	SUSPECT MEDICAL DEVICE				
	Brand Name				7
	Common Device Name			-	1
1	Procode				$\dashv$

Receipt No: RCT-105326 FDA 3500 Form

					_
	Manufacturer Name				
Г	City				
$\vdash$	State			,	
	Model #	,			
H	Lot#				
r	Catalog #		p m successor and a successor		
<u> </u>	Expiration Date				
$\vdash$	Serial #				
$\vdash$	Unique Identifier (UDI) #				
	Operator of Device	Health Professional  Lay User/Patient  Other			
	Other				
	If Implanted, Give Date		9	a a	
	If Explanted, Give Date		*		
	Is this a single-use device that was reprocessed and reused on a patient?	v			
	If Yes for the above field, Enter Name and Address of Reprocessor		1.		
	Fecal Microbiota Transplant-10/18	8/2017-10/18/2017			
F.	L OTHER (CONCOMITANT) ME	EDICAL PRODUCTS		1 of 1	
Pared	Product Name				
	Strength		If Other		
-	Therapy Start Date				
H	Therapy End Date		· · · · · · · · · · · · · · · · · · ·		
	2500555				
9	REPORTER  Last Name				-41-
-	First Name	161			
	Address		(6)		
-	City	\N/	101		-
_	State/Province/Region		\ /	***************************************	
-	Country				-
-	ZIP/Postal Code				_
-	Phone				
-	Email				_
	Health Professional?	Yes		, a	-
-	Occupation	Physician	If Other		
1	- Couperon	,			

Receipt No: RCT-105326	FDA 3500 Form

Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer	
If you do NOT want your identity disclosed to the manufacturer, please mark this box:		

Receipt No: RCT-106521 FDA 3500 Form

All dates displayed in the report are in	EST(GMT-05:00) time zone
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Basic Details			
Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	High		
FDA Received Date	19-Dec-2017	CTU Received Date	19-Dec-2017
CTU Triage Date			
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group		-	
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)	
	E OBEN (OBEN-O	70E-100-010@1da.rms.gov) (E2B)	
Contact		ACTOR SCIENCES IN THE SCIENCES	
Case First Name	Last Name	Email Address	Phone
Reporter		(b) (6)	
		(b) (6)	
A PATIENT INFORMATION			
Patient Identifier (In Confi	dence) (b) (6)		
Age	159		
Date of Birth	(b) (6)		
Sex	Female		
Weight	62.7 kg(s)	The state of the s	
Ethnicity (Check single be answer)	est Hispanic/Latino		
Race (Check all that apply	/) Asian		
	American Indian or Ala	skan Native	
	Black or African Americ	can	
	White		
	Native Hawaiian or Oth	er Pacific Islander	
B. ADVERSE EVENT, PR	ODUCT PROBLEM		
Check all that apply	Adverse Event		
	Product Use Error		
	Product Problem (e.g.,	defects/malfunctions)	
		Manufacturer of Same Medicine	
Outcome Attributed to Adv Event (Check all that apply	Death		*
Event (oncor an that appl	Life-threatening		
	Hospitalization - initial o	or prolonged	
	Other Serious (Importar		
	Disability or Permanent	•	*
	Congenital Anomaly/Bir		
Date of Death	Required Intervention to	o Prevent Permanent Impairment/Damage (Dev	ices)
Date of Event	28-Oct-2017		
Date of this Report	19-Dec-2017		
		and Martin C. V. and an incident of the Control of	
Describe Event, Problem o	AL STOTE OF STREET STREET		

Receipt No: RCT-106521 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2017-81601 | Department: CBER | RCT No.: RCT-106521 | CTU Triage Date: 19-12-2017 | AER #: 14302

575 | Total Pages: 4

Describe Event, Problem, or Product Use Error: Patient received a fecal microbial transplant on October 18, 2017 for chronic pouchitis symptoms which included abdominal pain, frequency and urgency. She reported abdominal discomfort, bloating and blood per rectum 10 days after fecal transplant (This was reported through MedWatch on 10/31/2017). She has continued to have some abdominal discomfort associated with nausea that she has dealt with through diet modification. Her vital signs and weight remains unchanged. This is an update for her follow up clinic visit which occurred on November 20, 2017 but we filled out the wrong reporting form. I received notice from Dr. Qun Wang yesterday that we submitted the wrong reporting form.

## Relevant Tests/Laboratory Data, Including Dates

Chemistry and CBC normal 12/1/2017: Na 139, Potassium 4, Cl 105, CO2 23, BUN 12, Cr 0.63, glucose 89 CBC 6.3, hbg 14.3, hematocrit 40.5, platelets 370

## Other Relevant History, Including Preexisting Medical Conditions

Patient with a pre-existing condition of chronic pouchitis with abdominal pain, urgency, and frequency, and history of ulcerative colitis.

## C, PRODUCT AVAILABILITY Product Available for Evaluation? Yes (Do not send product to FDA)

Returned to Manufacturer on

D. SUSPECT PRODUCTS			16	र्जी (
Product Name	Fecal transplant			
Strength		If Other		
Manufacturer/Compounder			2	
NDC# or Unique ID				
Lot Number				
Dose or Amount	250 ml millilitre(s)	If Other		
Frequency	Other	If Other	once	
Route	Rectal	If Other		
Therapy Start Date	18-Oct-2017			
Therapy End Date	18-Oct-2017			
Therapy Duration		If Other		
Diagnosis or Reason for Use (indication)	ulcerative colitis associ	ated chronic pouchitis		
Is the Product Compounded?	Yes		, , , , , , , , , , , , , , , , , , , ,	
Is the Product Over-the-Counter?		***		
Expiration Date				
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply			
Event Reappeared after Reintroduction ?	Doesn't Apply			

## E. SUSPECT MEDICAL DEVICE **Brand Name** Common Device Name Procode

Receipt No: RCT-106521 FDA 3500 Form

	Manufacturer Name		· · · · · · · · · · · · · · · · · · ·			_
	City					
T	State		-			_
	Model #					_
	Lot#	,				-
1	Catalog #					_
	Expiration Date					-
	Serial #					-
	Unique Identifier (UDI) #					
	Operator of Device	Health Professional Lay User/Patient Other				
	Other					
	If Implanted, Give Date					_
	If Explanted, Give Date					
	Is this a single-use device that was reprocessed and reused on a patient?					
	If Yes for the above field, Enter Name and Address of Reprocessor					_
	CONCOMITANT MEDICAL PROD					
F,	OTHER (CONCOMITANT) ME	EDICAL PRODUCTS	and and		1 of 1	2000
	Product Name	,				
_	Strength		If Other			
	Therapy Start Date		v			
	Therapy End Date					_
G.	REPORTER					2000
	Last Name	/1- \ /				
	First Name	$I \cap I$	6			
	Address	(b) (	UI		97	
		\ \ \				
	State/Province/Region			•		
	Country					
	ZIP/Postal Code				-	
	Phone					
	Email					
	Health Professional?	Yes	33			
	Occupation	Physician	If Other			٦

FDA 3500 Form Receipt No: RCT-106521

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2017-81601 | Department: CBER | RCT No.: RCT-106521 | CTU Triage Date: 19-12-2017 | AER #: 14302
575 | Total Pages: 4

Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
If you do NOT want your identity disclosed to the manufacturer, please mark this box:	

CTU No.: FDA-CDER-CTU-2018-2629 | Department: CBER | RCT No.: RCT-112431 | CTU Triage Date: 10-01-2018 | AER #: 143715 79 | Total Pages: 4

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Debils						
Company Unit	CDER-CTU	Originating Account	FAERS			
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500			
Priority	High	<u> </u>				
FDA Received Date	09-Jan-2018	CTU Received Date	09-Jan-2018			
CTU Triage Date						
Report Type	Spontaneous	Report Classification	Drug			
Assign To	User		, i			
User/Group						
Forward to Department	CDER (CDER-C	SE-RSS-CTU@fda.hhs.gov) (E2B)				
Contact						
Case First Name	Last Name	Email Address	Phone			
Reporter		(h) (6)				
		(b) (6)				
A PATIENT INFORMATION		<b>建设的的国际公司的</b>				
Patient Identifier (In Confidence)	(b) (6)					
Age						
Date of Birth	(b) (6)					
Sex	Female					
Weight	62.7 kg(s)					
Ethnicity (Check single best answer)	Hispanic/Latino					
Race (Check all that apply)	Asian					
	American Indian or Alas	skan Native				
	Black or African American					
	White					
	Native Hawaiian or Othe	er Pacific Islander				
B. ADVERSE EVENT, PRODUC	T PROBLEM					
Check all that apply	Adverse Event		*			
	Product Use Error					
	Product Problem (e.g., defects/malfunctions)					
Outcome Attributed to Adverse	Problem with Different N	Manufacturer of Same Medicine				
Event (Check all that apply)	Death					
	Life-threatening					
	Hospitalization - initial or prolonged					
	Other Serious (Important Medical Events)  Disability or Permanent Damage					
	Congenital Anomaly/Birt					
		Prevent Permanent Impairment/Damage (Devi	ces)			
Date of Death						
Date of Event	04-Jan-2018					
Date of this Report	09-Jan-2018					
Describe Event, Problem or Prod	uct Use Error					

Receipt No: RCT-112431 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2018-2629 | Department: CBER | RCT No.: RCT-112431 | CTU Triage Date: 10-01-2018 | AER #: 143715 79 | Total Pages: 4

Describe Event, Problem, or Product Use Error: Patient received a fecal microbial transplant on October 18, 2017 for chronic pouchitis symptoms which included abdominal pain, frequency and urgency. She reported abdominal discomfort, bloating and blood per rectum 10 days after fecal transplant (This was reported through MedWatch on 10/31/2017). She has continued to have some abdominal discomfort associated with nausea that she has dealt with through diet modification. Her vital signs and weight remains unchanged. (This was also reported previously.) When we called her to schedule her 3 month follow up she stated she was having abdominal pain and was headed to the hospital. She was admitted to the hospital on (b) (6)

She was afebrile with normal WBC 6.5. Her WBC and vitals have remained normal. She was treated for recurrent pouchitis with steroids, rifaximin, and budesonide (previous regimen). Gl did a flexible sigmoidoscopy and found the pouch to be normal, but a small ulcer at the junction of pouch and ileum.

## Relevant Tests/Laboratory Data, Including Dates

(b) (6) WBC 6.5 (b) (6) WBC 5.4 (b) (6) WBC 4.7

#### Other Relevant History, Including Preexisting Medical Conditions

Patient has a pre-existing condition of chronic pouchitis with abdominal pain, urgency, frequency and history of ulcerative colitis. She was admitted to the hospital in (b) (6) (prior to fecal transplantation) for these symptoms.

# C. PRODUCT AVAILABILITY Product Available for Evaluation? Yes (Do not send product to FDA) Returned to Manufacturer on

SUSPECT PRODUCTS			1011	
Product Name	Fecal Transplant			
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID			A	
Lot Number		8		
Dose or Amount	250 ml millilitre(s)	If Other		
Frequency	Other	If Other	once	
Route	Rectal	If Other		
Therapy Start Date	18-Oct-2017			
Therapy End Date	18-Oct-2017			
Therapy Duration		If Other		
Diagnosis or Reason for Use (indication)	chronic pouchitis		,	
Is the Product Compounded?	Yes			
Is the Product Over-the-Counter?			¥,	
Expiration Date				
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply	8		
Event Reappeared after Reintroduction?	Doesn't Apply			

E.	SUSPECT MEDICAL DEVICE	-
	Brand Name	

Page 2 of 4

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Receipt No: RCT-112431

FDA 3500 Form

CTU No.: FDA-CDER-CTU-2018-2629 | Department: CBER | RCT No.: RCT-112431 | CTU Triage Date: 10-01-2018 | AER #: 143715 79 | Total Pages: 4

Common Device Name	,	$\neg$
Procode		+
Manufacturer Name		+
City		+
State		
Model #		
Lot#		-
Catalog #		+
Expiration Date		+
Serial #		+
Unique Identifier (UDI) #		+
Operator of Device	Health Professional Lay User/Patient Other	
Other		+
If Implanted, Give Date		+
If Explanted, Give Date		-
Is this a single-use device that was reprocessed and reused on a patient?		
If Yes for the above field, Enter Name and Address of Reprocessor		
OTHER (CONCOMITANT) M	EDICAL PRODUCTS	600
CONCOMITANT MEDICAL PROD		
F. OTHER (CONCOMITANT) M	EDICAL PRODUCTS 1 of 1	
Product Name		
Strength	If Other	+
Therapy Start Date		+
Therapy End Date		$\top$
B. REPORTER		
Last Name		
First Name	/h\ /6\	+
Address	(b) (6)	+-
City		+
		+
State/Province/Region		-
Country ZIP/Postal Code		
ZIP/Postal Code		

Generated by: SYSTEM

Phone Email

Generated on:

09-Jan-2018 15:45:28

Receipt No: RCT-112431 FDA 3500 Form

CTU No.: FDA-CDER-CTU-2018-2629 | Department: CBER | RCT No.: RCT-112431 | CTU Triage Date: 10-01-2018 | AER #: 143715 79 | Total Pages: 4

Health Professional?	Yes			
Occupation	Physician	If Other		
Also Reported to	Manufacturer/C User Facility Distributor/Impo			
If you do NOT want your identity disclosed to the manufacturer, please mark this box:				

FDA 3500B Form Receipt No: RCT-133909

CTU No.: FDA-CDER-CTU-2018-23812 | Department: CBER | RCT No.: RCT-133909 | CTU Triage Date: 13-03-2018 | AER #: 14630 379 | Total Pages: 4

All dates	displayed in	the report a	are in	EST(GMT	-05:00)	time zone
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	ayed in the report are in EST(G	IM I -05:	00) time zone			
Basic Del	The state of the s	CDE	D CTU	Origi	esting Assoupt	EAEDS
Company Unit		CDER-CTU			nating Account	FAERS
Source Me	edium 	MWO (Drug)		Sour	ce Form Type	E2B XML 3500B
Priority		High	İ			
FDA Rece	ived Date	13-N	Mar-2018	СТО	Received Date	13-Mar-2018
CTU Triag	e Date					
Report Typ	oe .	Spor	ntaneous	Repo	rt Classification	Drug
Assign To		User				
User/Grou	p			-		
Forward to	Department	Ø	CDER (CDER-OS)	E-RSS-CT	J@fda.hhs.gov) (E2B)	
					3-71-7	
Contact						
Case	First Name		Last Name		Email Address	Phone
Reporter	Thetrane		zaci name		The state of the s	
				(b) (6		
	- About the Problem					
	nd of problem was it?				4	
	all that apply)				uding new or worsening sympto	oms)
•					have or led to a problem	* "
		Noticed a problem with the quality of the product				
	(1) (1) (-)	Had problems after switching from one product maker to another maker				
	of the following happen? all that apply)	Hospitalization - admitted or stayed longer				
(0.100.1		Required help to prevent permanent harm (for medical devices only)				
		Disability or health problem  Birth defect				
			fe-threatening			9
		H	eath			
+			ther serious/important m	nedical incider	nt	
	e problem occurred		ec-2017			
Tell us wh	at happened and how	li hap	The state of the s	The second secon	letails as possible)	
I am a 6	62 year old	7.0	(b) (6)	, (b) (4)	-ital HCM My savelage	I received my fecal
negative	n(b) (4)October 12, 201	a mon	cember 1 2017 I de	ship with m	y husband. After my diag	nosis his serology showed IgG
positive	for HSVI, IgM negative, H	le has	no history of herpe	s oral or ge	enital. It would seem he o	contracted this as a child as
		n. Ope	n Biome, the source	ce of the fe	cal <sup>(D)</sup> (4) does not scree	en donors for HSVI or HSV2.
This inc	ident was reported to the	fected	(b) (6), (b) (4)	b) (4), a	nd to Open Biome. I am	told that Open Biome feels that
there is no possibility that I was infected through the fecal (b) (4) I have two concerns: 1. It is certainly possible, although not previously reported, that HSV1 is transmissible through the fecal product. 2. Even if they did screen their donors there is no way to be sure the feces is from the stated donor as specimens are brought in to the lab, not collected while the donor is in the						
					ROSCIO R. O.	
(b) (6)	this deserves serious inve	esugai	ion, it is a major pu	iblic riealtri	lisk.	(b) (6)
List any re	levent tests or laborate	ory da	ta if you know th	rem (Inclu	ide dates)	
	III lab data available for yo				4	
	4					

CTU No.: FDA-CDER-CTU-2018-23812 | Department: CBER | RCT No.: RCT-133909 | CTU Triage Date: 13-03-2018 | AER #: 14630 379 | Total Pages: 4

8	eation B - About the Products				1011
	Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	fecal transplant (b	b) (4)		
	Name of the company that makes (or compounds) the product	Open Biome			
	Is the Product Compounded? (Your health professional may be able to help you identify whether the drug was compounded.)				
	Is the Product Over-the-Counter?	,			
	Expiration date			3,	
	Lot number				
	NDC number			v	
	Strength		If Other		
	Quantity		If Other		
	Frequency		If Other		
	How was it taken or used	Oral	If Other		
	Date the person first started taking or using the product	10-Oct-2017			
	Date the person stopped taking or using the product				
	Did the problem stop after the person reduced the dose or stopped taking or using the product?	No			
	Did the problem return if the person started taking or using the product again?	¥	-		
	Do you still have the product in case we need to evaluate it?	No		*	
Mi	y was the person using the pr	oduct? (such as w	that condition was it suppo	sed to treat)	
	post infectious irritable bowel disea	ase			
de	ction C - About the Medical De	vice			
1	Name of medical device				
1	Name of the company that makes the medical device				
)th	er identifying information (The ate them)	model, calalog, lo	ot, serial, or UDI number, a	and the expiration date, if yo	งบ อุลก
			,		
+	Model #				
+	Catalog #				
$\perp$		×			

Receipt No: RCT-133909

#### FDA 3500B Form

CTU No.: FDA-CDER-CTU-2018-23812 | Department: CBER | RCT No.: RCT-133909 | CTU Triage Date: 13-03-2018 | AER #: 14630 379 | Total Pages: 4

Serial #				
Lot#				
Unique Identifier (UDI) #				
Expiry Date				
Was someone operating the medical device when the problem occurred?	n			
For implanted medical devices of	DNLY (such as pacemakers, breast implants, etc.)			
Date the implant was put in	Date the implant was taken out (If relevant)			
Section D - About the Person W	ho Had the Problem			
Person's Initials	(b) (6)			
Sex	Female			
Age (specify unit of time for age)	62 Year(s)			
Date of Birth				
Weight	51.75 kg(s)			
Ethnicity (Choose only one)	Not Hispanic/Latino			
Race (Check all that apply)	American Indian or Alaskan Native  Native Hawaiian or Other Pacific Islander  Asian  White  Black or African American			
	tuch as diabetes, high blood pressure, cancer, heart disease, or others)			
Please list all allergies (such as to	o drugs, foods, pollen or others)			
Suita				
List any other important information	on about the person (such as smoking, pregnancy, alcohol use, etc.)			
lst all current prescription medic	ations and medical devices being used.			
Valtrex 500 mg po qd				
 _ist all over-the-counter medicatio	ons and any vitamins, minerals, supplements, and herbal remedies being used.			

Generated by: SYSTEM

Generated on:

13-Mar-2018 11:45:24

Receipt No: RCT-133909 FDA 3500B Form

CTU No.: FDA-CDER-CTU-2018-23812 | Department: CBER | RCT No.: RCT-133909 | CTU Triage Date: 13-03-2018 | AER #: 14630 379 | Total Pages: 4

JF. OTFIER (CONCOMITANT) M	EDICAL PRODUCTS 1 of 1
Product Name	
Strength	If Other
Therapy Start Date	
Therapy End Date	
Section E - About the Person FI	lling Out This Form
Last name	/L\ /C\
First name	(b) (6)
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	
Telephone number	
Email address	
Today's date	13-Mar-2018
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	
If you do NOT want your identity disclosed to the manufacturer, place an X in this box:	

CTU #: FDA-CD TRESELFOM 9-58042 | Department: CBER | RCT #: RCT-168349 | CTU Triage Date: 23-Jun-2018 | AER #: 15167898 | Total Pages: 1

U.S. Department of Health and Human Services

# MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of 3

Form Approved: OMB No. 0910-0291, Expires: 9/30/2018 See PRA stalement on reverse.

FDA USE ONLY

Triege unit
sequence #

FDA Rec. Date

	Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month			3.	Dose or Amount		Frequency	Route			-	
	abbreviation, and 4-digit year, for example, 01-Jul-2015.			#1							٦	
	A. PATIENT INFORMATION				30mL		once	nasoge	stric	tube ]		
	1. Patient Identifier 2. Age X Year(s) Month	(s) 3. Sex	4. Weight	#2								
	5 Week(s) Days(s	Female	18									
	or Date of Birth (e.g., 08 Feb 1925	3	□њ	4. Da	4. Dates of Use (From/To for each) (If unknown, B. Event Abated Aff							
	In Doublesses	X Male	⋉ kg		e duration, or best es			(yy) Stop	ped or D	ose Reduce	d?	
				#1 5/22/2018, one time admin				#1	#1 Yes No X Doesn't			
	5.a. Ethnicity (Check single best enswer)			#2 5. Diagnosis or Reason for Use (indication) #1						appl	<u> </u>	
								#2 🔲	Yes 🗌	No 🗌 Does		
									apply			
	B. ADVERSE EVENT, PRODUCT PROBLEM			40					10. Event Reappeared After			
	the second secon								Reintroduction?			
	Check all that apply    X   Adverse Event			6. Is the Product 7. Is the Product Over-					_ #1 ☐ Yes ☐ No ☒ Doesn't apply			
					mpounded?		the-Counter?					
	Product Use Error Problem with Different Manufacturer of Same Medicine			#1	TYes X No	#1 [	#1 Yes X No		#2 Yes No Doesn't apply			
	2. Outcome Attributed to Adverse Event (Check ell that apply)			1								
	Death Include date (dd-mmm-yyyy):			i				No				
				B. Ex	piration Date (dd-m/	mm-yyyy	•					
	Hospitalization - initial or prolonged			#1.			#2			*	_	
¥	Other Serious (Important Medicel Events)			E 8	SUSPECT MEDI	CALID	EVICE					
5	Required Intervention to Prevent Permanent Impairment/Damage (Devices)			1. Bn	and Name							
Ď	3. Date of Event (dd-mmm-yyyy) 4. Date of this Report (dd-mmm-yyyy)											
BLACK INK	05 - 24 - 2018 06 - 21 - 2018			2, Co	mmon Device Name	e				2b. Procod	e	
(i)	5. Describe Event, Problem or Product Use Error			II <del></del>			04-4-					
USE	patient presented with fever/sepsis in the setting of			3. Ma	nufacturer Name, C	ity and	State					
RI	central venous catheter 2 days after fecal microbiota											
0	transplant (FMT). Clinical presentation suggested			4 880	del#	116	ot#		5 Opp	rator of Devi		
TYPE OR	sepsis. Stabilized with IV fluids and abx in ED,			4. 1010	odel #	-	7L #F		□ He		Ce	
L				Catal	Da #	E	piration Dat	e (dd-mmm-yyyy)	1 - 5-	fessional		
SE	(Continue on page 3)								Lev User/Patient			
PLEASE	6. Relevant Tests/Laboratory Data, Including Dates			Seria	1#		nique Identif		OII	ier		
ک	Positive blood cultures as per abov	Positive blood cultures as now shows									_	
-	Positive blood cultures as per above					If Explanted, G	planted, Give Date (dd-mmm-yyyy)					
1			-	6. If I	mplanted, Give Date	e (ou-min						
-			-	6. If I			-					
Ŧ		Continue	in page 3)	8. ls t	his a single-use de	vice tha	t was					
<b>.</b>	7. Other Relevant History, including Preexisting Medic	(Continue o	g.,	8. is t	this a single-use de processed and reus	vice tha	t was patient?	☐ Yes	 □ No			
<b>.</b>	Other Relevant History, including Preexisting Medic allergies, pregnancy, smoking and alcohol use, liver/kid	(Continue o	g., :.)	8. is t	his a single-use de	vice tha	t was patient?	☐ Yes	 □ No			
±		Continue of the conditions (e. iney problems, etc.	g., :.)	8. is t	this a single-use de processed and reus	vice tha	t was patient?	☐ Yes	 □ No	-		
	allergies, pregnancy, smoking and alcohol use, liver/kid	(Continue of the problems, etc.)  th (b) (continue of the problems)	g., :) 6)	8. is t	this a single-use de processed and reus	vice tha	t was patient?	☐ Yes	 □ No			
	allergies, pregnancy, smoking and alcohol use, liver/kid Medically complicated 5 year old wi	(Continue of the problems, etc.)  th (b) (disease, christelesse, christelesse, christelesse)	g., :) 6) ronic	8. ls t rep 9. lf Y	this a single-use de processed and reus 'es to item 8, Enter	vice tha ed on a Name a	t was patient? nd Address	Yes	□ No			
	allergies, pregnancy, smoking and alcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart	(Continue of the problems, etc.)  th (b) (continue of the problems)	g., :) 6) ronic	8. ls t rep 9. lf Y	this a single-use de processed and reus es to item 8, Enter	vice tha ed on a Name a	t was patient? nd Address	Yes of Reprocesso	□ No			
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	allergies, pregnancy, smoking and alcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send products)	(Continue of the post to FDA)	g., (5) (6) (onic (3) (on page3)	8. is to rep 9. if Y	this a single-use de processed and reus es to item 8, Enter ITER (CONCO	vice tha ed on a Name a DMITAI	t was patient?  nd Address (  Nij) (VIED)(  es (Exclude to	Yes of Reprocesso  AL PRODU	□ No r  UCTS nt)	e on page	3)	
¥	allergies, pregnancy, smoking and alcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  G. PROBUCT AVAILABILITY	(Continue of the problems, etc.)  th (b) (disease, chr.)  (Continue of the problems, etc.)	s. 6) conic sun page:3)	8. is to rep 9. if Y	this a single-use de processed and reus es to item 8, Enter	vice tha ed on a Name a DMITAI	t was patient?  nd Address (  Nij) (VIED)(  es (Exclude to	Yes of Reprocesso  AL PRODU	□ No r  UCTS nt)	,	3)]	
¥ .	allergies, pregnancy, smoking and alcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  G. PROBUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product and produc	(Continue of the post to FDA)	s. 6) conic sun page:3)	8. is to rep 9. if Y	this a single-use de processed and reus es to item 8, Enter ITER (CONCO	vice tha ed on a Name a DMITAI	t was patient?  nd Address (  Nij) (VIED)(  es (Exclude to	Yes of Reprocesso  AL PRODU	□ No r  UCTS nt)	,	3)]	
<u>.</u>	allergies, pregnancy, smoking and alcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send products)	(Continue of the problems, etc.)  th (b) (disease, chr.)  (Continue of the problems, etc.)	s. 6) conic sun page:3)	8. is to rep 9. if Y	this a single-use de processed and reus (se to item 8, Enter of the second and the second and the second and the second and Address and Address	vice tha ad on a Name a Name a DMITAI apy date	t was patient?  nd Address of Add	Yes of Reprocesso  CAL PRODUCE  TENTINE TO THE TENT	UCTS	,	3)]	
	allergies, pregnancy, smoking and alcohol use, liverkid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product)  Yes No Returned to Manufacturer of the congenitation of the congenita	(Continue of the problems, etc.)  th (b) (disease, characteristics) (Continue of the problems, etc.)  in (Continue of the problems, etc.)  in (dd-mmm-yyyy),  oduct label)  #1 - NDC, # or L	S., (A) (B) (CONIC TO PROPERTY OF THE PROPERTY	8. is to rep 9. if Y	this a single-use de processed and reus (se to item 8, Enter of the second and the second and the second and the second and Address and Address	vice tha ad on a Name a Name a DMITAI apy date	t was patient?  nd Address of Add	Yes of Reprocesso  CAL PRODUCE  TENTINE TO THE TENT	UCTS	,	3)]	
	allergies, pregnancy, smoking and alcohol use, iver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product yes No Returned to Manufacturer of D. SUSPECT PRODUCTS  1. Name, Manufacturer/Compounder, Strength (from product)	il Contlinue of the problems, etc.  th (b) (disease, chr.  il Contlinue of the problems, etc.  il Contlinue of the problems, etc.  il Contlinue of the problems, etc.	S., (A) (B) (CONIC TO PROPERTY OF THE PROPERTY	8. is to rep 9. if Y	this a single-use de processed and reus (se to item 8, Enter of the second and the second and the second and the second and Address and Address	vice tha ad on a Name a Name a DMITAI apy date	t was patient?  nd Address of Add	Yes of Reprocesso  CAL PRODUCE  TENTINE TO THE TENT	UCTS	,	3)]	
<u>.</u>	allergies, pregnancy, smoking and elcohol use, liver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  G. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product Yes No Returned to Manufacturer of the Suspect Products  D. SUSPECT PRODUCTS  1. Name, Manufacturer/Compounder, Strength (from products)  #1 - Name and Strength	(Continue of the problems, etc.)  th (b) (disease, characteristics) (Continue of the problems, etc.)  in (Continue of the problems, etc.)  in (dd-mmm-yyyy),  oduct label)  #1 - NDC, # or L	S., (A) (B) (CONIC TO PROPERTY OF THE PROPERTY	8. is to rep 9. if Y	this a single-use de processed and reus (se to item 8, Enter of the second and the second and the second and the second and Address and Address	vice tha ad on a Name a Name a DMITAI apy date	t was patient?  nd Address of Add	Yes of Reprocesso  AL PRODU	UCTS	,	3)]	
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1	allergies, pregnancy, smoking and elcohol use, iver/kid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  G. PRODUCTAVALABILITY  2. Product Available for Evaluation? (Do not send product and product a	il (Continue of the problems, etc. the problems, et	9. 6) conic = in page:3) )	8. is to rep 9. if Y Produ 1. Na:	this a single-use de processed and reus (es to item 8, Enter de l'es to	DMITAL apy date	t was patient?  nd Address of Add	Yes of Reprocesso  CAL PRODUCE TEALMENT OF ever	Ontinii	e on page		
<u>.</u>	allergies, pregnancy, smoking and elcohol use, liverikid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product and electric products)  Tyes No Returned to Manufacturer of the products and products.  D. SUSPECT PRODUCTS  1. Name, Manufacturer/Compounder, Strength (from products)  #1 - Name and Strength open biome FMT 30mL solution  #1 - Manufacturer/Compounder	il Continue of the problems, etc. the (b) (disease, chr. il Continue of the problems, etc. il Continue of th	9. 6) conic = in page:3) )	8. is to rep 9. if Y Produ 1. Na. 2. He:	this a single-use de processed and reus (es to item 8, Enter de l'es to	DMITAL apy date	t was patient?  nd Address of Add	Yes of Reprocesso  CAL PRODUCE TEALMENT OF ever	□ No  P  UGTS  nt)  Continu	e on page Reported to: Ulacturer/		
	allergies, pregnancy, smoking and elcohol use, liverikid  Medically complicated 5 year old wi  (b) (6) complex congenital heart  C. PRODUCT AVAILABILITY  2. Product Available for Evaluation? (Do not send product and electric products)  Tyes No Returned to Manufacturer of the products and products.  D. SUSPECT PRODUCTS  1. Name, Manufacturer/Compounder, Strength (from products)  #1 - Name and Strength open biome FMT 30mL solution  #1 - Manufacturer/Compounder	il Continue of the problems, etc. the (b) (disease, chr. il Continue of the problems, etc. il Continue of th	9. 6) conic = in page:3) )	8. is to rep 9. if Y Produ 1. Na: 2. He: X 5. if y	this a single-use de processed and reus (es to item 8, Enter de l'es to	DMITAL SALES OF THE PROPERTY IN THE PROPERTY I	t was patient?  Ind Address of Ad	Yes of Reprocesso  CAL PRODUCE  TREATMENT OF EVER  THE COMMENT OF THE COMMENT  THE COMMENT OF THE COMMENT  TH	□ No  P  Detts  nt)  Continue  A. Also F  Men  Com	e on page		

CTU #: FDA DER CTU 2018-90481 | Department: CBER | RCT #: RCT-202754 | CTU Triage Date 02-Oct-2018 | AER #: 15463533 |
Total Pages: 1

See PRA statement on reverse. U.S. Department of Health and Human Services For use by user-facilities, Mir Report # Food and Drug Administration importers, distributors and manufacturers MEDWATCH for MANDATORY reporting UF/Importer Report # Page 1 of 3 FDA Use Only Dose Route Used Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month Frequency abbreviation, and 4-digit year; for example, 01-Jul-2015. 250 ml ×ι A. PATIENT INFORMATION 4. Weight 1. Patient Identifier 3. Sex Year(s) Month(s) 250 ml ☐ Week(s) ☐ Days(s) Female 9 Event Abated After Use 4. Therapy Dates (If unknown, give duration) from/ 08 Enh 10251 ☐ Ib Stopped or Dose Reduced? ☐ Male to (or best estimate)) (dd-mmm-yyyy) (6 b) ☐ kg In Confidence 21/Feb/ZOID #1 Yes No Doesn't 5.b. Race (Check all that apply) 5.a. Ethnicity (Check apply 12018 single best answer) Asian American Indian or Alaskan Native 5. Diagnosis for Use (Indication) #2 Yes No Doesn't ☐ Hispanic/Latino White Black or African American apply M Not Hispanic/Latino Native Hawaiian or Other Pacific Islander 10. Event Reappeared After **B. ADVERSE EVENT OR PRODUCT PROBLEM** Reintroduction? #1 Yes No Doesn't Adverse Event and/or Product Problem (e.g., defects/malfunctions) apply 6. Is the Product s the Product Over-2. Outcome Attributed to Adverse Event (Chock all that apply) Compounded? the-Counter? #2 Yes No Doesn'i Death include date (dd-mmm-yyyy): No No Yes Yes 01 Life-threatening Disability or Permanent Damage ☐ Yes Yes W No Congenital Anomaly/Birth Defects Hospitalization - initial or prolonged 8. Expiration Date (dd-mmm-yyyy) Other Serious (Important Medical Events) #2 Required Intervention to Prevent Permanent Impairment/Damage (Devices) D. SUSPECT MEDICAL DEVICE 3. Date of Event (dd-mmm-yyyy)
29-04N2017 4. Date of this Report (dd-mmm-yyyy) 1. Brand Name PLEASE TYPE OR USE BLACK 5. Describe Event or Problem 2b. Procode 2. Common Device Name 3. Manufacturer Name, City and State 5. Operator of Device Lot # 4 Model # (Continue on page 3) Health Professional 6. Relevant Tests/Laboratory Data, Including Dates Expiration Date (dd-mmm-vvvv) Catalog # Lay User/Patient Other Unique Identifier (UDI) # Serial # 6. If Implanted, Give Date (dd-mmm-yyyy) 7. If Explanted, Give Date (dd-mmm-yyyy) (Continue on page 3) 7. Other Relevant History, Including Preexisting Medical Conditions (e.g., 8. Is this a single-use device that was ☐ No Yes reprocessed and reused on a patient? allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.) 9. If Yes to Item 8, Enter Name and Address of Reprocessor (Continue on page 3) 10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: C. SUSPECT PRODUCT(S) 1. Name, Manufacturer/Compounder, Strength 11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) #1 - NDC # or Unique ID #1 - Lol # (Continue on page 3) #2 - NDC # or Unique ID E. INITIAL REPORTER Name and Address #2 - Lot # #2 - Manufacturer/Compounder 2. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (Continue on page 3) 4. Initial Reporter Also Sent 2. Health Submission of a report does not constitute an admission that medical Professional? Report to FDA personnel, user facility, importer, distributor, manufacturer or product GI Yes No Yunk Yes No caused or contributed to the event.